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16	UNITED STAT	TES DISTRICT COURT	
17	NORTHERN DIS	STRICT OF CALIFORNIA	
18	EDWIN HARDEMAN,	Case No.: 3:16-cv-00525-VC	
19	Plaintiff,	MONSANTO COMPANY'S NOTICE OF	
20		MOTION TO DISMISS AND MEMORANDUM OF POINTS AND	
,	V.	AUTHORITIES IN SUPPORT OF MOTION	
21	MONSANTO COMPANY AND JOHN DOES 1-50,	TO DISMISS	
22	,	Hearing Date: April 7, 2016	
23	Defendant.	Time: 10:00 a.m.	
24		Judge: Hon. Vince Chhabria	
		Courtroom: 4, 17 th Floor	
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TO PLAINTIFF AND HIS COUNSEL AND TO THE CLERK OF THE COURT:

PLEASE TAKE NOTICE that on April 7, 2016 at 10:00 A.M. or as soon thereafter as the matter may be heard in Courtroom 4, 17th Floor, of the above captioned court, located at 450 Golden Gate Avenue, San Francisco, California, the Honorable Vince Chhabria presiding, defendant Monsanto Company ("Monsanto") will, and hereby does, move for dismissal of all of plaintiff Edwin Hardeman's claims against Monsanto.

This Motion is made under Federal Rule of Civil Procedure 12(b)(6) on the grounds that (1) all of plaintiff's claims based on a claim of inadequate warning, no matter how denominated, are preempted under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq.; and (2) all of plaintiff's non-warning design defect claims are foreclosed pursuant to Restatement (Second) of Torts § 402A comments j and k.

PLEASE TAKE FURTHER NOTICE that this Motion to Dismiss is based upon this Notice and its Memorandum of Points and Authorities, the concurrently-filed Request for Judicial Notice, and such further arguments and evidence as Monsanto may submit with its Reply or as the Court may consider at the hearing of this motion.

DATED: March 1, 2016

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MONSANTO'S NOTICE OF MOTION AND MEMO ISO MOTION TO DISMISS 3:16-cv-00525

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO DISMISS

I. ISSUES TO BE DECIDED

- 1. Whether plaintiff's warnings-based state law claims are preempted by the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.*, as implemented by the Environmental Protection Agency.
- 2. Whether plaintiff's non-warning design defect claims regarding the alleged inherent carcinogenicity of Monsanto's Roundup® products are barred under comments j and k to the Restatement (Second) of Torts § 402A, as adopted under California law.

II. INTRODUCTION

Plaintiff Edwin Hardeman alleges that exposure to Monsanto Company's ("Monsanto") Roundup® caused him to develop non-Hodgkin's lymphoma ("NHL"). Roundup®'s active ingredient, glyphosate, is the most widely-used weed killer in the United States. Since its introduction in 1974, the U.S. Environmental Protection Agency ("EPA") repeatedly has concluded, including as recently as last year, that exposure to Roundup® does not cause cancer. *See infra* at 9.

Plaintiff's arguments fail to state a claim and must be dismissed under Fed. R. Civ. P. 12(b)(6). As an initial matter, plaintiff's warnings-based claims, whether brought under negligence, strict liability, or breach of implied warranty theories (claims I, III, and IV in plaintiff's Amended Complaint) are preempted under FIFRA. Second, because plaintiff's claims rest upon the alleged inherent carcinogenicity of Roundup® products, his non-warnings-based design defect claim (claim II) is precluded in California by comments j and k to the Restatement (Second) of Torts § 402A. For these reasons, as set forth more fully herein, plaintiff's complaint should be dismissed in its entirety.

III. STATEMENT OF RELEVANT FACTS

The ability to feed the world's growing population while the amount of available farmland continues to dwindle is key to preventing a global humanitarian, agricultural, and economic crisis.

this total (Bridges; WSSA, 1992).").

Weeds reduce essential crop yield by displacing and contaminating crops, or rendering crops inedible. Herbicide use can prevent over 70% of potential crop yield losses due to weeds.¹

Glyphosate is "the most important herbicide" developed in the post-World War II era.² Glyphosate-based herbicides first became commercially available in 1974 when, after four years of testing by its research scientists, Monsanto introduced Roundup[®], a mixture of glyphosate and surfactants (chemical compounds commonly found in products such as soaps that allow glyphosate to travel on the surface of the weed to growing areas).³ Farmers apply Roundup[®] before crops are planted or, where glyphosate resistant seed is used, during the growing process.

As documented in numerous scientific analyses, glyphosate is not toxic to humans or animals.⁴ EPA, which has broad authority to regulate all herbicides under FIFRA, has for

not used, this loss was estimated to be \$19.6 billion. Losses in field crops accounted for 82% of

¹ E.C. Oerke, *Crop losses to pests*, 144 J. Agric. Sci. 31, 38 (2006). In economic terms, the average estimated annual monetary loss—including losses in field crops, damage to farming equipment, and increased crop production costs—caused by weeds would exceed \$15 billion in the United States alone in the absence of herbicides. *See* Dwight D. Lingenfelter, *Introduction to Weeds: What are Weeds and Why Do We Care?*, PennState Extension, http://extension.psu.edu/pests/ipm/schools-childcare/schools/educators/curriculum/weeds/introweeds ("In 1991, the estimated average annual monetary loss caused by weeds with current control strategies in the 46 crops grown in the United States was \$4.1 billion. If herbicides were

² Stephen O. Duke & Stephen B. Powles, *Glyphosate: A Once-In-A-Century Herbicide*, 64 Pest Mgmt. Sci. 319, 319 (2008) [hereinafter *Glyphosate: A Once-In-A-Century Herbicide*].

³ See William S. Curran & Dwight D. Lingenfelter, *Adjuvants for Enhancing Herbicide Performance*, Penn State Extension, http://extension.psu.edu/pests/weeds/control/adjuvants-for-enhancing-herbicide-performance.

⁴ See Keith R. Solomon et al., Human Health and Environmental Risks from the Use of Glyphosate Formulations to Control the Production of Coca in Colombia: Overview and Conclusions, 72 J. Toxicology & Envtl. Health 914, 919 (2009); Keith R. Solomon et al., Coca and Poppy Eradication in Colombia: Environmental and Human Health Assessment of Aerially Applied Glyphosate, 190 Revs. Envtl. Contamination & Toxicology 43, 106 (2007); Gary M. Williams et al., Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans, 31 Reg. Toxicology & Pharmacology 117, 129 (2000) (reviewing over 188 documents either in published scientific literature or submitted to regulatory agencies assessing the safety of glyphosate, and concluding that glyphosate "is considered to be practically nontoxic by all these routes of exposure").

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decades found glyphosate to be "one of the most safely-used pesticides in the U.S." and repeatedly has concluded that glyphosate exposure does not cause cancer. As recently as October 21, 2015, Dr. William Jordan, Deputy Director of EPA's Office of Pesticide Programs, testified before a Senate Committee that EPA's current safety evaluation of glyphosate, announced in April 2015, confirms that scientific literature "does not provide evidence to show that [g]lyphosate causes cancer and does not warrant any change in EPA's cancer classification for [g]lyphosate." The one federal court to consider allegations regarding the carcinogenicity of glyphosate in a personal injury suit rejected those allegations as lacking reliable scientific support. See Arias v. DynCorp, 928 F. Supp. 2d 10, 24-25 (D.D.C. 2013) (excluding as unreliable expert's causation opinion that glyphosate-based herbicides have carcinogenic effects).

Plaintiff ignores this record of safety and instead relies on the International Agency for Research on Cancer's ("IARC") recent "cancer hazard" listing of glyphosate as a "probable carcinogen." IARC is located in Lyon, France; it is not a regulatory agency, and none of its determinations are binding on any country. Although IARC purports to "identify cancer hazards," it acknowledges that its methodology allows for the designation of a substance as a "probable" carcinogen "even when risks are very low with known patterns of use or exposure." For example, IARC does not take into account levels of exposure, methods of exposure, or other factors central to a determination of whether a substance can actually cause cancer in humans under real world exposure scenarios.⁸ Based on this same methodology, IARC has classified a wide variety of commonly-used substances and exposures as "probable" or "known" carcinogens,

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⁵ Letter from EPA Assistant Administrator Stephen L. Johnson to Secretary of State Colin Powell dated Aug. 19, 2002, http://www.state.gov/j/inl/rls/rpt/aeicc/13237.htm. ⁶ See Agriculture Biotechnology: A Look at Federal Regulation and Stakeholder Perspectives:

² 24

Hearing Before the S. Comm. on Agr., Nutrition, & Forestry, 114th Cong. (2015) (statement of Dr. William Jordan, Deputy Director of EPA's Office of Pesticide Programs), http://www.ag.senate.gov/templates/watch.cfm?id=74793e67-5056-a055-64af-0e55900753b4, at time stamp 55:05 – 56:20 ("EPA 2015 Desk Statement").

²⁵

⁷ See IARC Monographs Questions and Answers, 3 (2015), http://www.iarc.fr/en/mediacentre/iarcnews/pdf/Monographs-Q&A.pdf.

²⁷ 28

 $^{^8}$ See IARC, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Preamble, 2 (Jan. 2006), http://monographs.iarc.fr/ENG/Preamble/currenta2objective0706.php.

1	including bacon, hot dogs, and red meat; alcoholic beverages; salted fish; shiftwork; frying	
2	food; 13 and dry cleaning. 14	
3	Plaintiff alleges that his diagnosis in February 2015 with NHL is the result of exposure to	
4	Roundup® that was sprayed on his property "beginning in the 1980's" and "[f]or many years	
5	on a regular basis." Am. Compl. & Jury Demand ("Am. Compl."), ¶¶ 112-113, ECF No. 6.	
6	Plaintiff asserts a variety of claims, all of which revolve around Monsanto's alleged failure to	
7	warn of the risk of cancer. See id. ¶¶ 121-187.	
8	IV. ARGUMENT	
9	A. Plaintiff's Failure to Warn Claims Are Preempted Under FIFRA.	
10	Plaintiff's claims for failure to warn, whether brought under strict liability, negligence, or	
11	breach of implied warranty theories, are preempted by FIFRA—the pervasive federal regulatory	
12	scheme implemented by EPA—and by EPA's repeated determination that glyphosate does not	
13	cause cancer. See 7 U.S.C. § 136v(b); Bates v. Dow Agrosciences LLC, 544 U.S. 431, 454 (2005)	
14	("[A] manufacturer should not be held liable under a state labeling requirement subject to §	
15	136v(b) unless the manufacturer is also liable for misbranding as defined by FIFRA."); see also	
16	Mirzaie v. Monsanto Co., No. CV 15-04361 DDP (FFMx), 2016 WL 146421, at *2 (C.D. Cal.	
17	Jan. 12, 2016) (citing <i>Bates</i> and holding that plaintiffs' state-law claims regarding Roundup [®]	
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20	⁹ IARC, <i>IARC Monographs Evaluate Consumption of Red Meat and Processed Meat</i> (Oct. 26, 2015), http://www.iarc.fr/en/mediacentre/pr/2015/pdfs/pr240_E.pdf.	
21	¹⁰ IARC, Consumption of Alcoholic Beverages, Vol. 100E (2012),	
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27 28 were preempted under FIFRA because they "would require [Monsanto] to alter its [EPAapproved] label"), appeal docketed, No. 16-55228 (9th Cir. Feb. 12, 2016).

> FIFRA Expressly Preempts State Labeling Requirements That Differ From 1. Those Required By EPA.

In order to ensure the exclusivity of EPA's comprehensive regulatory scheme over product labeling, section 136v(b) of FIFRA contains an express preemption clause, which limits the role of states in regulating warnings for pesticides and herbicides. Section 136v(b) provides that states "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." The Supreme Court explained that the term "requirements" as used in section 136v(b) reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties. Bates, 544 U.S. at 443. Thus. section 136v(b) preempts any statutory or common-law rule that would impose a warning requirement that diverges from EPA's labeling decisions under FIFRA. *Id.* at 453-54; see also Mirzaie, 2016 WL 146421, at *2 (holding that plaintiffs' false advertising claims regarding Roundup® were preempted because "[t]here can be no dispute that Plaintiffs seek to impose a labeling requirement different or in addition to that required under FIFRA, as the Roundup label to which Plaintiffs object, and which Plaintiffs seek to alter, was approved by the Environmental Protection Agency in 2008"); Red v. Kroger Co., No. CV 10-01025 DMG (MANx), 2010 WL 4262037, at *7 (C.D. Cal. Sept. 2, 2010) (holding that pursuant to *Bates*, "a state law labeling requirement would not be pre-empted by FIFRA only 'if it is equivalent to, and fully consistent with' the applicable FIFRA subchapter") (emphasis added). 16

¹⁵ The U.S. Supreme Court has twice confirmed this interpretation of section 136v(b). In *Riegel* v. Medtronic, Inc., 552 U.S. 312, 324 (2008), the Court cited Bates in explaining that FIFRA's "provision pre-empting state 'requirements' pre-empted common-law duties." 552 U.S. at 324 (citing Bates). In Mutual Pharmaceutical Co. v. Bartlett, the Court reiterated that under Bates, a state common-law claim imposes a "pre-emptable 'requirement.'" 133 S. Ct. 2466, 2479-80 (2013).

¹⁶ See also In re Syngenta Ag Mir 162 Corn Litig., Nos. MDL 2591, 14-MD-2591-JWL, 2015 WL 5607600, at *23 (D. Kan. Sept. 11, 2015) (holding that plaintiffs' "failure-to-warn claims are preempted by FIFRA" and thus "dismiss[ing] any claim based on an alleged failure to warn to the

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Under FIFRA, a manufacturer seeking to register a herbicide must submit a proposed abel and certain supporting data to EPA. Bates, 544 U.S. at 438 (citing 7 U.S.C. §§ 36a(c)(1)(C), (F)). Registration constitutes "prima facie evidence that the [herbicide], its abeling, and packaging comply with [FIFRA's] registration provisions." 7 U.S.C. § 136a(f)(2). 'In evaluating a [herbicide] registration application, [EPA] assess[es] a wide variety of potential numan health and environmental effects associated with use of the product [including] plotential human risk[]...[of] cancer."¹⁷ EPA "evaluate[s] and approve[s] the language that appears on each [herbicide] label to ensure the directions for use and safety measures are appropriate to any potential risk." *Id.*; see also 40 C.F.R. § 156.10(i)(1)(i); 40 C.F.R. § 156.60. EPA will approve a pesticide application only if "[t]he Agency has determined that the product is not misbranded as that term is defined in FIFRA . . . and its labeling and packaging comply with he applicable requirements of the Act." 40 C.F.R. § 152.112(f) (emphasis added).

Moreover, in determining whether to register a pesticide under FIFRA, EPA also must consider whether the pesticide is safe under section 408 of the Federal Food Drug and Cosmetics Act ("FDCA"). This assessment includes the safety of tolerance levels for pesticide chemical residues in or on a food. 21 U.S.C. § 346a(b)(2)(A)(i). A residue tolerance is deemed "safe" only f EPA "determine[s] that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." 21 U.S.C. § 346a(b)(2)(A)(ii); see Nat. Res. Def. Council v. E.P.A., 735 F.3d 873, 885 (9th Cir. 2013) (discussing EPA safety assessment under section 408 of FDCA).

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extent that such claim is based on a lack of warnings in materials accompanying the products"); Wilgus v. Hartz Mountain Corp., No. 3:12-CV-86, 2013 WL 653707, at *6-7 (N.D. Ind. Feb. 19, 2013) (citing *Bates* and holding that where plaintiffs' complaint directly challenged the labeling of the product and alleged that the defendants failed to adequately warn of potential dangers associated with it, plaintiffs' claims were preempted by FIFRA); Smith v. Hartz Mountain Corp., No. 3:12-cv-00662, 2012 WL 5451726, at *2-3 (N.D. Ohio Nov. 7, 2012) (same).

¹⁷ See EPA, About Pesticide Registration, http://www2.epa.gov/pesticide-registration/aboutpesticide-registration.

Unlike with claims of efficacy such as those that were at issue in *Bates*, EPA may not waive an applicant's data requirements pertaining to the human safety of a herbicide. ¹⁸ EPA cannot register a herbicide or approve its labeling unless the agency concludes that the herbicide "will perform its intended function without unreasonable adverse effects on the environment," including human health. 7 U.S.C. § 136a(c)(5)(C); 7 U.S.C. § 136(bb) (defining "unreasonable adverse effects on the environment' to include human health risks). As *Bates* explains, EPA's decision to stop evaluating pesticides for efficacy was specifically based upon its need to devote its resources to assessing potential environmental and health risks. See Bates, 544 U.S. at 440.

> EPA Has Rejected Plaintiff's State Law Argument That Monsanto Should 2. Be Required to Warn About a Purported Association Between Glyphosate and Cancer or Other Chronic Health Risks.

Here, plaintiff alleges under negligence, strict liability, and breach of implied warranty theories that because Monsanto failed to "adequately inform and warn Plaintiff of the serious and dangerous risks associated with the use of and exposure to glyphosate and/or Roundup, including, but not limited to, the risk of developing NHL," he was eventually diagnosed with NHL. Am. Compl. ¶ 96; see also id. ¶¶ 114, 131, 154, 164, 187. In total, plaintiff alleges a "failure to warn" in nineteen paragraphs in the claims section of the Complaint. See, e.g., id. ¶ 127(b) (alleging under the Negligence claim that Monsanto "[f]ailed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Roundup"); ¶ 160 (alleging under the Strict Liability claim that "[t]he defective condition of Roundup was due in part to the fact that it was not accompanied by proper warnings regarding its

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¹⁸ See 7 U.S.C. § 136a(c)(5) ("the Administrator may waive data requirements pertaining to efficacy"); cf. Bates, 544 U.S. at 440 (basing decision not to preempt claims based upon alleged inefficacy of herbicide on fact that EPA "had 'stopped evaluating pesticide efficacy for routine label approvals almost two decades ago"); see also Meaunrit v. Pinnacle Foods Grp., LLC., No. C 09-04555 CW, 2010 WL 1838715, at *10 (N.D. Cal. May 5, 2010) (noting that *Bates* ruling was based on EPA's lack of review of efficacy claims and preempting claims that challenged federal safety determinations under express preemption clauses in federal statutes identical to preemption clause in FIFRA).

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carcinogenic qualities and possible side effects, including, . . . developing non-Hodgkin's lymphoma"). ¹⁹

Plaintiff's allegations are directly contradicted not only by EPA's prior express approvals of the product and product label but also by EPA's consistent findings that glyphosate is *not* carcinogenic to humans.²⁰ Specific findings of safety include:

- "In June 1991, EPA classified glyphosate as a Group E [carcinogen]—one that shows evidence of non-carcinogenicity for humans—based on the lack of convincing evidence of carcinogenicity in adequate studies." EPA, *Glyphosate: Reregistration Eligibility Decision (RED) Facts*, 2 (Sept. 1993), http://archive.epa.gov/pesticides/reregistration/web/pdf/0178fact.pdf. *See* Request for Judicial Notice, Ex. A (filed concurrently).
- "No evidence of carcinogenicity." Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,943 (Sept. 27, 2002) (to be codified at 40 C.F.R. pt. 180). *See* Request for Judicial Notice, Ex. B (filed concurrently).
- "Glyphosate has no carcinogenic potential." Glyphosate; Pesticide Tolerance, 69 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004) (to be codified at 40 C.F.R. pt. 180). *See* Request for Judicial Notice, Ex. C (filed concurrently).
- "There is [an] extensive database available on glyphosate, which indicate[s] that glyphosate is not mutagenic, not a carcinogen, and not a developmental or reproductive toxicant." Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008) (to be codified at 40 C.F.R. pt. 180). *See* Request for Judicial Notice, Ex. D (filed concurrently).
- "EPA has concluded that glyphosate does not pose a cancer risk to humans." Glyphosate; Pesticide Tolerances, 78 Fed. Reg. 25,396, 25,398 (May 1, 2013) (to be codified at 40 C.F.R. pt. 180). *See* Request for Judicial Notice, Ex. E (filed concurrently).
- "In 2014, EPA reviewed over 55 epidemiological studies conducted on the possible cancer and non-cancer effects of [g]lyphosate. Our review concluded that this body of research does not provide evidence to show that [g]lyphosate causes cancer and does not warrant any change in the EPA's cancer classification for [g]lyphosate." EPA 2015 Desk Statement at time stamp 55:17-55:37. *See* Request for Judicial Notice, Ex. F (filed concurrently).

¹⁹ See also Am. Compl. ¶¶ 124(f), 124(g), 124(h), 127, 127(c), 127(d), 127(e), 149, 161, 162, 163, 165, 167, 168, 173, 174, 175.

²⁰ See Request for Judicial Notice, Ex. A – F (filed concurrently).

Plaintiff's failure to warn claims seek to impose "labeling requirement[s] different or in addition to" these consistent findings of EPA. *Compare Mirzaie*, 2016 WL 146421, at *2; *and Red*, 2010 WL 4262037, at *7, *with*, *e.g.*, Am. Compl. ¶ 127(d) (alleging Monsanto is negligent for having "[f]ailed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Roundup"). Accordingly, plaintiff's warnings-based claims are preempted by FIFRA and must be dismissed.²¹

B. Plaintiff's Non-Warnings Design Defect Claims Are Barred By Restatement (Second) of Torts § 402A.

Plaintiff's design defect claims focus on glyphosate's and/or Roundup®'s alleged "carcinogenic properties." *See* Am. Compl. ¶¶ 32, 44, 81, 124(d), 167, 168. Plaintiff does not allege that there is an alternative design that would avoid this claimed carcinogenic effect. Rather, he alleges that both glyphosate and Roundup® are inherently and unavoidably dangerous. *See*, *e.g.*, *id.* ¶ 83 ("[N]umerous human and animal studies have evidenced the carcinogenicity of glyphosate and/or Roundup."); *id.* ¶ 136 ("Roundup was in an unsafe, defective, *and inherently dangerous condition*, which was dangerous to users. . . .") (emphasis added); *see id.* ¶¶ 140, 146, 185 (alleging Roundup® is "inherently dangerous and unsafe," has "established health risks inherent with its normal, intended use," and is sold in an "inherently dangerous condition").

Based on plaintiff's allegations, his design defect claims are governed by the "closely related" comments j and k to the Restatement (Second) of Torts § 402A, and plaintiff is limited to claims that the warnings accompanying the product are deficient. *See Brown v. Superior Court (Abbott Labs.)*, 227 Cal. Rptr. 768, 772-73 (Cal. Ct. App. 1986), *review granted and opinion superseded*, 723 P.2d 1248 (Cal. 1986), *aff'd sub nom. Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988).²² Thus, plaintiff's non-warnings based claims should be dismissed.²³

²¹ To the extent that plaintiff alleges that these consistent EPA findings of safety are based upon fraud, *see*, *e.g.*, Am. Compl. ¶¶ 106-108, 124(f), 124(p), 181, 183, plaintiff's claims also are impliedly preempted as impermissible fraud-on-the-agency claims. *See Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1204-06 (9th Cir. 2002).

²² See also Canifax v. Hercules Powder Co., 46 Cal. Rptr. 552, 558 (Cal. Ct. App. 1965) (summarizing comments j and k as stating the rule that "a product, although faultlessly made,

As adopted in California, comments j and k address the class of products that carry unavoidable dangers that cannot be designed away without destroying their utility. David G. Owen, The Puzzle of Comment J, 55 Hastings L.J. 1377, 1382 (2004). Such products, "accompanied by proper warnings, are not in a 'defective condition unreasonably dangerous' with respect to the unavoidable dangers inherent in products of this type." *Id.* Comments j and k reflect the policy determination in Section 402A that:

Because there is no way (other than by providing warnings) that manufacturers of such products can minimize the inherent dangers of such products without also destroying their utility, there is no good reason in corrective iustice against risks of harm economics to force manufacturers to insure consumers they have chosen to accept by using products with inherent risks they fully understand.

Id. at 1389.

California courts have specifically applied comment j in cases involving herbicides. See Oakes v. E.I. Du Pont de Nemours & Co., 77 Cal. Rptr. 709, 710, 712-13 (Cal. Ct. App. 1969) (explaining that manufacturer of "weed-killing [] products" was required to warn only of "special danger[s]" they have knowledge of or "by the application of reasonable, developed human skill and foresight" should have knowledge of).²⁴ Pursuant to comment j, "a product bearing . . . a

may nevertheless be deemed 'defective' . . . if it is unreasonably dangerous to place the product in the hands of a user without a suitable warning and the product is supplied and no warnings is given").

²³ Section 402A is stated as an adjunct of strict liability, and California courts have found that comments j and k also reflect "well settled rules already a part of the law of negligence." Skaggs v. Clairol Inc., 85 Cal. Rptr. 584, 587 (Cal. Ct. App. 1970) (discussing comment j); see also Carlin v. Superior Court, 920 P.2d 1347, 1357-58 (Cal. 1996) (explaining that comment k is based on negligence principles); Ortho Pharm. Corp. v. Chapman, 388 N.E.2d 541, 550 (Ind. App. 1979) (citing *Skaggs* for proposition that negligence and strict liability are "functionally interchangeable" under section 402A in cases involving inherently dangerous products).

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²⁴ Other courts have done likewise. See Ackerman v. Am. Cyanamid Co., 586 N.W.2d 208, 220-21 (Iowa 1998) (applying comment j in herbicide case and holding that "[u]nder the applicable products liability law, it is clear that if American Cyanamid had placed directions or warnings on its label that, if followed, would have made the product safe for use, the product would not be unreasonably dangerous and liability would be avoided"); Oregon Azaleas, Inc. v. W. Farm Serv., Inc., No. Civ. 00-1348-KI, 2001 WL 34045733, at *4 (D. Or. Aug. 20, 2001), aff'd in part, rev'd in non-relevant part, 65 F. App'x 101 (9th Cir. 2003) (applying comment j in rejecting design

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warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous." *Oakes*, 77 Cal. Rptr. at 712 (quoting comment j); *see also Johnson v. Am. Standard, Inc.*, 179 P.3d 905, 910-11 (Cal. 2008) (applying comment j). Where "there [is] no evidence . . . that defendant's product was defectively 'manufactured,' in the literal sense of the word, defendant [can] be found liable under the Restatement rule set forth in comment j to section 402A only if it *negligently* failed to label its product in such a manner as to warn consumers of the dangerous ingredient contained therein." *Skaggs*, 85 Cal. Rptr. at 588 (emphasis in original). ²⁵

In *Brown v. Superior Court*, the California Supreme Court applied comment k and held that manufacturers of prescription drugs cannot be held strictly liable for design defect based upon the theory that the drug was defectively designed. 751 P.2d 470, 479-80 (Cal. 1988). Rather, a drug manufacturer may be held liable only if "it failed to warn of a defect of which it either knew or should have known." *Id.* at 476; *see id.* at 476-77 (adopting comment k as *per se* rule in cases involving prescription drugs); *see also id.* at 481 (explaining that consistent with comment j, defendants could not be held liable for failing to warn of "alleged defects in the drug that were neither known by defendants nor scientifically knowable at the time the drug was distributed"). The court reasoned that "[p]ublic policy favors the development and marketing of beneficial new [products], even though some risks, perhaps serious ones, might accompany their introduction" Thus, "the imposition of a harsher test for liability would not further the public interest" *Id.* at 479-80.

"Brown's logic and common sense are not limited to drugs." Anderson v. Owens-Corning Fiberglas Corp., 810 P.2d 549, 556 (Cal. 1991). California courts thus have extended comment k protection to other medical products, including inflatable penile prostheses, ²⁶ breast

defect claim involving pesticide).

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²⁵ "Other courts have also held that where adequate warnings are given, a product is neither defective nor unreasonably dangerous." *Gauthier v. AMF, Inc.*, 788 F.2d 634, 635-36 (9th Cir. 1986) (Montana law and citing other cases); *see also Glover v. BIC Corp.*, 6 F.3d 1318, 1323 (9th Cir. 1993) (Oregon law).

²⁶ *Hufft v. Horowitz*, 5 Cal. Rptr. 2d 377, 378, 383-84 (Cal. Ct. App. 1992).

implants,²⁷ and intrauterine devices.²⁸ Courts in other jurisdictions have applied comment k to chemicals and other compounds, including asbestos-containing insulation,²⁹ benzene,³⁰ cleaning compounds,³¹ perchloroethylene,³² and permanent hair wave products.³³

In *Ruiz-Guzman v. Amvac Chemical Corp.*, the Supreme Court of Washington applied comment k to a pesticide. 7 P.3d 795, 803 n.10 (Wash. 2000), *opinion after certified question answered* 243 F.3d 549 (9th Cir. 2000). The court reasoned that "a determination that pesticides can *never* be unavoidably unsafe products within the ambit of comment k would seem to defy common sense." *Id.* at 803 (emphasis in original). Accordingly, "a product-by-product approach to the application of comment k [to pesticides] is warranted." *Id.* The court held that even if "its product cannot be made safer for its intended use, a pesticide manufacturer could demonstrate the product serves an important enough function (e.g., in the realm of food production) so as to justify its unavoidable risks." *Id.*

Because plaintiff alleges that glyphosate is unavoidably unsafe, his design defect claims are governed by comments j and k, and Monsanto's only duty is to provide a proper warning. *See Bates*, 544 U.S. at 450 n.25 ("Given the inherently dangerous nature of pesticides, most safety gains are achieved not through modifying a pesticide's design, but by improving the warnings and instructions contained on its label."). Notwithstanding its alleged inherent risks, glyphosate use is justified by its significant value to society. According to U.S. Department of Agriculture scientist

²⁷ Artiglio v. Superior Court, 27 Cal. Rptr. 2d 589, 593-94 (Cal. Ct. App. 1994).

²⁸ Plenger v. Alza Corp., 13 Cal. Rptr. 2d 811, 818-19 (Cal. Ct. App. 1992).

²⁹ Borel v. Fibreboard Paper Prods. Corp., 493 F.2d 1076, 1091 (5th Cir. 1973); Daniels v. Combustion Eng'g, Inc., 583 S.W.2d 768, 772 (Tenn. Ct. App. 1978).

³⁰ Authement v. Ingram Barge Co., 977 F. Supp. 2d 606, 615 (E.D. La. 2013); Hall v. Ashland Oil Co., 625 F. Supp. 1515, 1518 (D. Conn. 1986).

³¹ Uptain v. Huntington Lab, Inc., 685 P.2d 218, 220 (Colo. App. 1984), aff'd, 723 P.2d 1322 (Colo. 1986).

³² Purvis v. PPG Indus., Inc., 502 So. 2d 714, 718 (Ala. 1987).

³³ Payne v. Soft Sheen Prods., Inc., 486 A.2d 712, 722 (D.C. 1985).

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Stephen O. Duke, "glyphosate more closely approximates to a perfect herbicide than any other[.]" *Glyphosate: A Once-In-A-Century Herbicide*, at 319.

As detailed above, glyphosate is unique in its high specificity towards an enzyme that is essential to plant growth but that is not present in animals or humans. See id. No other chemical classes or analogs are capable of targeting the enzyme this way. *Id.* Glyphosate's unique mode of action also is active on a wide range of plant species. *Id.* The "spectacular" adoption of glyphosate-resistant ("GR") crops is due to the fact that "the [specific] combination of glyphosate and a GR crop . . . provides better, simpler, cheaper and more flexible weed management than the conventional alternatives." Id. at 322. Plaintiff acknowledges that "Monsanto's glyphosate products are registered in more than 130 countries and are approved for weed control in more than 100 crops. No other herbicide active ingredient compares in terms of approved uses." Am. Compl. ¶ 31.

The aggregate welfare effects of glyphosate and GR crops are also considerable. For example, in 2001 alone, GR soybeans created more than \$1.2 billion of economic surplus at the global level, with the largest share, 53%, going to consumers. See Matin Qaim & Greg Traxler, Roundup Ready Soybeans in Argentina: Farm Level and Aggregate Welfare Effects, 32 Agric. Econ. 73, 73 (2005); see also Jan M. Lucht, Public Acceptance of Plant Biotechnology and GM Crops, 7 Viruses 4254, 4255 (2015) (By using crops engineered to be resistant to glyphosate and other herbicides, "[f]armer's profits increased by 68% on average Crop yields rose by 22%, the expense for pesticides declined by 39%.").

Although plaintiff may allege that glyphosate might have been "made safer if it was withheld from the market until scientific skill and knowledge advanced to the point at which additional dangerous side effects would be revealed," see Brown, 751 P.2d at 479, such a delay added to the delay required to obtain approval for release of the product and product label from EPA, "would not serve the public welfare." *Id.* Moreover, if Monsanto or other manufacturers of herbicide products were subject to strict liability, they might be "reluctant to undertake research programs" to develop beneficial new products, and "the additional expense of insuring against such liability . . . and of research programs to reveal possible dangers not detectable by available

Chief at Massachusetts General Hospital for Children) (2015) ("[Food insecurity] is often drived by economic limitations and often afflicting the most vulnerable children and the elderly	1	scientific methods" could place the cost of vital herbicide products "beyond the reach of those	
Chief at Massachusetts General Hospital for Children) (2015) ("[Food insecurity] is often drived by economic limitations and often afflicting the most vulnerable children and the elderly	2	who need it most" like poor, rural, and developing populations. See id; see also Agriculture	
by economic limitations and often afflicting the most vulnerable children and the elderly	3	Biotechnology, at time stamp 2:39:28 – 2:40:01 (Statement of Dr. Robert Kleinman, Physician in	
Enhanced, sustainable food production is essential [to addressing this problem] in both the developed and developing world."); Request for Judicial Notice, Ex. F (filed concurrently). Given "the public['s] interest in the development, availability, and reasonable price" of glyphosate, plaintiff's claims are governed by comments j and k, and Monsanto may only be he liable based upon an alleged failure to warn. See Brown, 751 P.2d at 477. Plaintiff's non-warnings strict liability and negligent design defect claims should be dismissed. V. CONCLUSION For the foregoing reasons, this Court should grant this motion and, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, dismiss this case in its entirety. DATED: March 1, 2016 Respectfully submitted, /s/ Richard A. Clark State Bar No. 39558 (frolark@pmcos.com) Katharine R. Latimer (pro hac vice application pending) (klatimer@hollingsworthllp.com) Eric G. Lasker (pro hac vice application pending) (clasker@hollingsworthllp.com) HOLLINGSWORTH LLP 1350 I Street, N.W. Washington, DC 20005 Feesimile: (202) 682-1639 Attorneys for Defendant MONSANTO COMPANY	4	Chief at Massachusetts General Hospital for Children) (2015) ("[Food insecurity] is often driven	
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For the foregoing reasons, this Court should grant this motion and, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, dismiss this case in its entirety. DATED: March 1, 2016 Respectfully submitted, Section Respectfully submitted, Section Respectfully sub	11	warnings strict liability and negligent design defect claims should be dismissed.	
12(b)(6) of the Federal Rules of Civil Procedure, dismiss this case in its entirety. DATED: March 1, 2016 Respectfully submitted, SKRichard A. Clark	12	V. CONCLUSION	
DATED: March 1, 2016 Respectfully submitted, /s/ Richard A. Clark Richard A. Clark Richard A. Clark State Bar No. 39558 (rclark@pmcos.com) Katharine R. Latimer (pro hac vice application pending) (klatimer@hollingsworthllp.com) Eric G. Lasker (pro hac vice application pending) (elasker@hollingsworthllp.com) HOLLINGSWORTH LLP 1350 I Street, N.W. Washington, DC 20005 Telephone: (202) 898-5800 Facsimile: (202) 682-1639 Respectfully submitted, /s/ Richard A. Clark Richard A. Clark State Bar No. 39558 (rclark@pmcos.com) Steven R. Platt State Bar No. 245510 (splatt@pmcos.com) PARKER, MILLIKEN, CLARK, O'HARA & SAMUELIAN. P.C. 555 S. Flower Street, 30th Floor Los Angeles, CA 90071 Telephone: (213) 683-6500 Facsimile: (213) 683-6669 Attorneys for Defendant MONSANTO COMPANY	13	For the foregoing reasons, this Court should grant this motion and, pursuant to Rule	
Joe G. Hollingsworth (pro hac vice application pending) (jhollingsworth@hollingsworthllp.com) Katharine R. Latimer (pro hac vice application pending) (klatimer@hollingsworthllp.com) Eric G. Lasker (pro hac vice application pending) (elasker@hollingsworthllp.com) HOLLINGSWORTH LLP 1350 I Street, N.W. Washington, DC 20005 Telephone: (202) 898-5800 Facsimile: (202) 682-1639 //s/ Richard A. Clark State Bar No. 39558 (rclark@pmcos.com) PARKER, MILLIKEN, CLARK, O'HARA & SAMUELIAN. P.C. S55 S. Flower Street, 30th Floor Los Angeles, CA 90071 Telephone: (213) 683-6500 Facsimile: (213) 683-6669 Attorneys for Defendant MONSANTO COMPANY	14	12(b)(6) of the Federal Rules of Civil Procedure, dismiss this case in its entirety.	
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	17 18 19 20 21 22 23 24 25	application pending) (jhollingsworth@hollingsworthllp.com) Katharine R. Latimer (pro hac vice application pending) (klatimer@hollingsworthllp.com) Eric G. Lasker (pro hac vice application pending) (elasker@hollingsworthllp.com) HOLLINGSWORTH LLP 1350 I Street, N.W. Washington, DC 20005 Telephone: (202) 898-5800	Richard A. Clark State Bar No. 39558 (rclark@pmcos.com) Steven R. Platt State Bar No. 245510 (splatt@pmcos.com) PARKER, MILLIKEN, CLARK, O'HARA & SAMUELIAN. P.C. 555 S. Flower Street, 30th Floor Los Angeles, CA 90071 Telephone: (213) 683-6500 Facsimile: (213) 683-6669 Attorneys for Defendant
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